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CALIFORNIA HEALTHCARE INSTITUTE

March 22, 2013

The Honorable Bonnie Lowenthal
California State Assembly
State Capitol, Room 3152
Sacramento, CA 95814

**RE: AB 1139 (Lowenthal) – OPPOSE UNLESS AMEMDED**

Dear Assembly Member Lowenthal:

On behalf of the California Healthcare Institute (CHI), the statewide public policy association representing California's innovative life sciences sector – biotechnology, pharmaceutical, medical device and diagnostics companies, venture capital firms, research universities and institutes and its 275,000 workers – I am writing to oppose AB 1139 unless it is amended. This legislation would update current law and allow pharmacists to substitute biologic medicines with a new and more affordable class of FDA-approved treatments called biosimilars, but fails to take the prudent step of requiring a patient's physician be notified the substitution has taken place.

Many of CHI's member companies work in the field of biologics. These cutting-edge medicines are used to treat patients who suffer from one or more serious chronic and often times debilitating and life-threatening illnesses. This new generation of treatments has transformed the health and lives of thousands of patients and has given them – and their families – hope for recovery.

In the next couple of years, *biosimilar* medications are expected to enter the U.S. healthcare market. Biosimilars are copies of an original biologic medicine and hold the promise of providing similar results as the original biologic at a lower price. However, unlike generic medicine, biosimilars are not structurally identical to the biologic products they seek to copy; thus the name biosimilar. Due to the sensitive nature of biologics, the slightest variation from the original biologic medicine can result in an immune response or other patient side effects. CHI represents companies responsible for making the original biologic and companies seeking to create biosimilars of these lifesaving medicines.

As important as these new therapies are to patients in California, it is just as important that public policy ensures the safety of the patients who rely upon them. We ask that AB 1139 be amended to require that a patient's physician is notified

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when a biosimilar medicine is substituted for a medication the doctor originally prescribed.

AB 1139 is on the right track to ensuring patients have access to life-saving, lower cost, FDA-approved biosimilars. It also needs to recognize the importance of tracking and tracing the use of sensitive medicines in the event of an adverse patient reaction.

For these reasons, we oppose AB 1139 unless it is amended. CHI would welcome the opportunity to work with the author's office to increase patient protections in AB 1139.

Sincerely,

Eve Bukowski
Vice President – State Government Affairs

cc: Members, Assembly Business, Professions and Economic Development